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1. This is a lawsuit against Cardinal Health, Inc. for violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the federal False Claims Act, 31 U.S.C. § 3729(a)-(b).

2. These violations relate to the pricing of prescription drugs covered by Medicaid and/or Medicare.

### **Medicaid**

3. When states purchase brand-name drugs on behalf of Medicaid beneficiaries on a fee-for-service basis, they generally pay the drug's estimated acquisition cost ("EAC") plus a dispensing fee. The EAC is the state Medicaid agency's best estimate of the price generally and currently paid by providers of a drug.

4. Most states use the Average Wholesale Price ("AWP") of a drug to determine its EAC. The AWP is the price the drug manufacturer reports to drug price compendia, such as the Red book. It represents the manufacturer's suggestion as to the price the wholesaler should charge a retail pharmacist. Other states determine EAC by adding a percentage markup to the Wholesale Acquisition Cost ("WAC") of the particular drug.

5. In Missouri, Medicaid pays pharmacies for brand-name drugs at a rate of 89.57% of AWP or 90% of WAC, whichever is lower. *See* 13 CSR 70-20.070. Pharmacies keep the difference between the amount Medicaid pays and their actual cost of acquiring the drugs from the manufacturer or wholesaler. This difference can be substantial, depending on the purchasing leverage of the pharmacy.<sup>1</sup>

6. To be reimbursed for a provided product, enrolled providers are required to submit a medical claim. In the case of pharmacies, such claims may be submitted either via form

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<sup>1</sup> Pharmacies also receive a dispensing fee for handling each Medicaid prescription. In Missouri, this fee is approximately \$4.09.

MO-8803 or POS, on-line claim format. Regardless of which claim method is used, the provider is required to identify the Medicaid beneficiary receiving the drug, the medication dispensed by the National Drug Code (“NDC”), the quantity dispensed, and the total charge for all services claimed.

7. Drug manufactures pay for the privilege of participating in state Medicaid programs. Through agreements with the Secretary of Health and Human Services, drug manufacturers provide rebates to state Medicaid agencies which help offset the amounts that Medicaid pays to pharmacies that dispense the manufactures’ drugs.

8. For brand-name drugs, the basic rebate is the greater of (a) 15.1% of the Average Manufacturer Price (“AMP”) of the drug or (b) the difference between the AMP and the “best price” for the drug. The AMP is the average price paid to the manufacturer by wholesalers for distribution to retail pharmacies like The Medicine Shoppe. The “best price” is the lowest price at which the manufacturer will supply the drug to any wholesaler, retailer, provider, HMO or nonprofit or governmental entity in the United States.<sup>2</sup> 42 U.S.C. § 1396r-8(c)(1)(C).

9. For generic drugs, the rebate is simply 11% of AMP. There is no “best price” adjustment.

10. The Department of HHS relies upon drug manufactures to provide the AMP and “best price” data from which rebates are calculated. If this data is inaccurate, i.e., if it does not truly reflect the average or best prices paid for drugs, the rebates may not properly offset the payments that Medicaid makes to pharmacies for dispensing the drugs. State Medicaid programs may end up overpaying for drugs.

### **Medicare**

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<sup>2</sup> There are certain statutory exceptions, such as the VA.

11. Prior to January 2006, Medicare provided only limited coverage for prescription drugs. Coverage was provided under Medicare Part B.

12. Under Medicare Part B, coverage was (and is) available for (a) injectable or intravenous drugs administered by a physician; (b) drugs administered through a covered item of durable medical equipment such as inhalants delivered through a nebulizer; and (c) certain drugs specifically listed in the Medicare statute, such as immunosuppressants and oral cancer drugs. Medicare pays the administering physician 95 percent of AWP for these drugs, less a 20 percent coinsurance payment due from the beneficiary. The physician keeps the difference between the amount Medicare pays, plus the coinsurance payment, and the physician's actual cost of acquiring the drugs.

13. Effective January 2006, Medicare began providing an optional drug benefit, known as Medicare Part D, to Medicare beneficiaries. Under Medicare Part D, the Centers for Medicare & Medicaid Services ("CMS") contracts with private insurance companies, known as Part D sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program. Sponsors may offer a stand-alone prescription drug plan or they can offer prescription drug coverage as part of a managed care plan, known as a Medicare Advantage Prescription Plan. Sponsors are required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to offer, at a minimum, a basic prescription drug benefit that is either the standard prescription drug benefit or is actuarially equivalent to the standard benefit.

14. To participate in the Medicare program, providers are required to certify, among other things, that

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and underlying transaction

complying with such laws, regulations, and program instructions (including but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

*See Medicare Enrollment Application, Form CMS-855S.*

### **The Cardinal Health Kickback**

15. Cardinal Health, Inc. ("Cardinal") distributes one-third of all pharmaceuticals, medical, lab and surgical products in the United States, and provides comprehensive financial, inventory, contract management and marketing services to retail, alternate care, and mail-order and hospital pharmacies. In addition, through its subsidiaries Medicine Shoppe International, Inc. ("MSI") and Medigap Pharmacies Incorporated ("MG"), Cardinal is the largest franchisor of independent community pharmacies in the U.S. There are nearly 1,000 domestic Medicine Shoppe Pharmacies and Medigap Pharmacy locations and more than 400 pharmacies in six other countries.

16. Relator Saleamua Inc. ("SI") is the former owner of seven locations of the Medicine Shoppe retail pharmacy franchise, all within the Kansas City, Missouri metropolitan area.

17. The Medicine Shoppe is a full-line retail pharmacy. It carries prescription and over-the-counter drugs, brand-name and generic, as well as medical equipment and devices that are sold directly to the consumer.

18. During the time period SI was a Medicine Shoppe franchisee, SI was required to pay MSI a franchise fee equal to 4 percent of gross sales.

19. The vast majority of prescription drugs carried by the Medicine Shoppe are covered by Medicaid and/or Medicare.

20. At all time relevant to this Complaint, SI submitted claims for reimbursement from the Medicaid and Medicare programs for drugs it dispensed.

21. Prior to 2006 and for a period of approximately 11 years, SI purchased prescription and over-the-counter drugs for its seven Medicine Shoppe locations through McKesson Corporation, a Cardinal competitor.

22. In early January 2006, Pete Pfankuch (“Pfankuch”), the New Business Development Manager for Cardinal, contacted SI and inquired whether it would be interested in switching distributors for its Medicine Shoppe stores. Cardinal offered SI an additional 2.3% discount off normal wholesale prices for the drugs SI purchased.

23. Because of its long history with McKesson and the possible costs and logistical headaches associated with moving to new distributor, SI informed Cardinal that it would not switch.

24. Shortly after receiving SI’s response, Cardinal made a second offer. This time Cardinal offered to give SI a 2.3% discount on the drugs it purchased from Cardinal and to pay SI \$50,000 for making the switch.

25. SI still would not budge. SI suggested, partly in jest, that Cardinal should raise its cash offer to \$100,000.

26. Cardinal agreed. It offered to give SI a 2.3% discount on the drugs it purchased from Cardinal and to pay SI \$100,000 for making the switch. SI tentatively accepted this offer.

27. SI contacted McKesson to inform McKesson that going forward, it would be purchasing its drugs from Cardinal. During the parties’ conversation, SI disclosed the remuneration it would be receiving for switching to Cardinal. McKesson responded by offering to pay SI \$150,000 to stay with McKesson.

28. Following McKesson’s offer, representatives from SI and McKesson met in person to attempt to hammer out a deal whereby SI would stay with McKesson. Despite

repeated prompting from SI, McKesson failed to present SI with a written contract containing the parties' agreed upon terms. The meeting ended without a firm deal in place.

29. The next day, Cardinal's representative, Pfankuch, contacted SI and said he had a "blank check" to get SI's business. A bidding war quickly ensued. Cardinal offered SI \$300,000 to switch. McKesson offered SI \$400,000 to stay. Cardinal raised its offer to \$440,000, to include a \$300,000 cash payment and a \$140,000 credit toward the purchase of Cardinal's PDX inventory tracking system.

30. McKesson could match the cash offer but could not match the 2.3% drug discount. Ultimately, SI decided to go with Cardinal. It accepted Cardinal's offer and signed a contract with Cardinal on or about January 23, 2006. Cardinal gave SI a check for \$440,000. Cardinal also gave SI the PDX system free of charge. A copy of the contract is attached hereto as Exhibit A.

31. This \$440,000 cash payment decreased the acquisition cost for the drugs SI purchased from Cardinal and therefore increased the spread between SI's cost and the amount SI received in Medicaid and Medicare reimbursements.

32. This \$440,000 cash payment constitutes a flagrant violation of the federal Anti-Kickback Statute and the False Claims Act.

33. At the time it accepted this payment, SI was unaware it was unlawful. SI was misled about the nature and effect of this payment.

34. At the time it made this cash payment, Cardinal knew it was unlawful. Cardinal intentionally misled SI about the nature and effect of this payment.

## **The Federal Anti-Kickback Statute**

35. As enacted in 1972, the federal Anti-Kickback statutes made it a misdemeanor to solicit, offer, or receive “any kickback or bribe in connection with” furnishing covered goods or services or referring a patient to a provider of those services. *See Social Security Amendments Act*, Pub.L. No. 92-603, §§ 242(b) and 242(c), 86 Stat. 1419 (1972).

36. Congress expanded the language in 1977 to prohibit the solicitation or receipt of “any remuneration (including any kickback, bribe, or rebate)” in return for referrals, to prohibit the offer or payment of such remuneration to induce referrals, and to make violations of the statutes a felony. *See Medicare-Medicaid Antifraud and Abuse Amendments*, Pub.L. No. 95-142, 91 Stat. 1175, 1181, 1182 (1977).

37. In 1980, the knowing and willful requirement was added, *Omnibus Reconciliation Act of 1980*, Pub.L. No. 96-499, 94 Stat. 2599, 2625 (1981), and in 1987, the Medicare and Medicaid statutes were combined into one statute (42 U.S.C. § 1320a-7b) and the Office of the Inspector General was authorized to exclude individuals and entities that violated the statutes from the Medicare and Medicaid programs. *See Medicare and Medicaid Patient and Program Protection Act of 1987*, Pub.L. No. 100-93, 101 Stat. 680, 681-682 (1989).

38. Currently, the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), provides in pertinent part:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in case or in kind-

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(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program,



shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than 5 years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-

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(B) to purchase, lease, order, or arrange for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than 5 years, or both.

39. Any person or entity that commits an act described in paragraph (1) or (2) of section 1320a-7b(b) is subject, in addition to any other penalties prescribed by law, to a civil money penalty of not more than \$50,000 for each such act, and is subject to an assessment of damages. 42 U.S.C. § 1320a-7a. In addition, the Secretary may exclude the person or entity from participation in federal health care programs and may direct appropriate state agencies to exclude the person or entity from participation in state health care programs as well. 42 U.S.C. § 1320a-7a(a); *see also* 42 U.S.C. § 1320a-7(a) and (b).

### **The False Claims Act**

40. The False Claims Act was enacted in 1863 to combat widespread fraud by government contractors during the Civil War. It provides that any person who (1) knowingly presents or causes to be presented to an official or employee of the United States Government a false or fraudulent claim for payment or approval, or (2) knowingly makes or uses a false record or statement to get a false or fraudulent claim paid or approved by the Government, or (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid, is liable to the Government for a civil penalty of \$5,000 to \$10,000 and treble damages. 31 U.S.C. § 3729(a).

41. In *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008), a recent seminal case in this area, the Supreme Court held that it was not necessary for a defendant to actually present for payment a false claim to the federal government to become liable under the FCA. “What [the FCA] demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting ‘a false or fraudulent claim paid or approved by the Government.’” *Id.* at 2130.

42. In *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259-60 (11th Cir.2005), the Eleventh Circuit held that a defendant who made a false certification of compliance with the Anti-Kickback Statute when submitting claims for Medicare reimbursement can be held liable under the FCA. It explained, “When a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the [False Claims] Act, for its submission of those false claims.” *Id.* at 1259.

43. Several other courts have followed the reasoning in *McNutt*, holding that false certification for the purpose of receiving a payment or benefit is the practical equivalent of a statutory false claim. *See e.g. United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir.2004) (citation omitted) (involving FCA claims for Medicare and Medicaid benefits); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir.2004) (“A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.”); *United States ex re. v. Thompson v. Comubia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir.1997) (“Thus, where the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or

regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.”); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F.Supp.2d 258, 264 (D.D.C.2002) (“Where the government pays funds to a party and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent”).

**Cause of Action – Violation of 31 U.S.C. § 3729(a)**

44. SI incorporates by reference the foregoing allegations as if fully set forth herein.

45. By giving SI a \$440,000 cash payment to induce SI to purchase drugs covered by Medicaid and Medicare, Cardinal violated 42 U.S.C. § 1320a-7b(b)(2)(B) (the Federal Anti-Kickback Statute), which provides: “whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than 5 years, or both.”

46. By giving SI a \$440,000 cash payment to induce SI to purchase drugs covered by Medicaid and Medicare, Cardinal caused SI to violate 42 U.S.C. § 1320a-7b(b)(1)(B) (the Federal Anti-Kickback Statute), which provides: “whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind ... in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for

which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than 5 years, or both.”

47. By violating and causing SI to violate 42 U.S.C. § 1320a-7b(b)(1) (the Federal Anti-Kickback Statute), Cardinal also violated 31 U.S.C. § 3729(a) (the Federal False Claims Act). Cardinal caused false claims—specifically, SI’s claims for Medicaid and Medicare reimbursement—to be presented to the Government for payment or approval.

48. SI’s claims were false because SI certified, as a condition for participating in the Medicare program, that it would not violate the federal Anti-Kickback Statute (SI violated the federal Anti-Kickback Statute by accepting a \$440,000 kickback).

49. Furthermore, the effect of the \$440,000 kickback was to lower the acquisition cost of the drugs SI purchased, and therefore to increase the spread between the acquisition cost and the reimbursement that SI received from Medicaid (as noted above, Missouri Medicaid pays pharmacies for brand-name drugs at a rate of 89.57% of AWP or 90% of WAC, whichever is lower). The greater the spread, the more profit SI made on the drugs it sold. This decrease in acquisition cost should have been passed on to Medicaid. The failure to do so amounts to a false claim concerning how much the drugs actually cost SI acquire.

50. The \$440,000 cash payment does not qualify as a “discount” within the meaning of the safe harbor regulation, 42 C.F.R. § 1001.952(h).

51. 42 C.F.R. § 1001.952(h) excludes discounts and other reductions in price from being classified as illegal remuneration under the federal Anti-Kickback Statute.

52. In its contract with SI, Cardinal attempted to characterize its \$440,000 payment as a discount. Section II, ¶ 9 of the Prime Vendor Agreement between Cardinal and SI provides:

If and to the extent any discount, credit, rebate or other purchase incentive is paid or applied by Cardinal Health with respect to the Products purchased under this Agreement, such discount credit, rebate or other purchase incentive shall constitute a “discount or other reduction in price,” as such terms are defined under the Medicaid/Medicare Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A) and the “safe harbor” regulations regarding discounts or other reductions in price set forth in 42 C.F.R. 1001.952(h)), on the Products purchased by Buyer or any Pharmacy under the terms of this Agreement.

*Id.*

53. Importantly, however, cash payments and cash equivalents, such as the \$440,000 payment made by Cardinal, are **not** considered discounts for purposes of safe harbor protection. *See* 42 C.F.R. § 1001.952(h)(5)(i). It was misleading for Cardinal to suggest otherwise.

54. The fact that Cardinal was willing to make such substantial payment (with such little negotiation) to SI to obtain SI’s business—and to attempt in writing to bring such payment within the “safe harbor” protection afforded by 42 C.F.R. § 1001.952(h)—suggests this is part of Cardinal’s normal business practices.

55. SI believes that its experiences with Cardinal were typical, and that further investigation will reveal that Cardinal has made similar deals with numerous other pharmacies, and that these deals have resulted in Medicare and Medicaid paying millions of dollars more than they should have paid for prescription drugs.

56. On information and belief, as a direct and proximate result of paying Medicare and Medicaid claims from pharmacies that had taken illegal kickbacks from Cardinal and so were not proper participants in the Medicare and Medicaid programs, the United States Treasury sustained millions of dollars in damages.

WHEREFORE, Relator demands judgment against Cardinal in the amount of three times the amount of claims paid by the United States Treasury to pharmacies who received illegal kickbacks from Cardinal, for a civil penalty against Cardinal in an amount between Five

Thousand Dollars (\$5,000) and Ten Thousand Dollars (\$10,000) for each violation of 31 U.S.C. § 3729(a) et seq., for the maximum amount allowed to the *qui tam* relator under 31 U.S.C. § 3730(d) of the False Claims Act, for its court costs and attorney's fees at prevailing rates, for expenses, and for such other and further relief as this Court deems just and appropriate.

**Jury Demand**

Relator requests trial by jury on all claims so triable.

Respectfully submitted,

**GRAVES BARTLE & MARCUS LLC**

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ATTORNEYS FOR RELATOR

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on November 12, 2008, a true and correct copy of the foregoing was served by first class, U.S. mail, postage prepaid, on

Joel F. May  
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